IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Serial No.: Divisional of U.S.S.N. 09/255,179

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For: MATRICES FORMED OF POLYMER AND HYDROPHOBIC COMPOUNDS FOR USE IN DRUG DELIVERY

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination, please amend the application as follows.

In the Specification

On page 1, after the title and before "Background of the Invention", please insert at the beginning of line 5 the following:

--This application is a divisional of U.S. Serial No. 09/255,179 filed February 22, 1999, which--

On page 1, line 5, please delete "This".

In the Claims

Please amend the claims as follows.

20. (Amended) A method for administering a therapeutic or prophylactic agent comprising

administering [the matrix of any of claims 1-15] a polymeric matrix for delivery of a therapeutic or prophylactic agent, wherein the matrix is formed of a biocompatible polymer having incorporated therein an therapeutic or prophylactic agent and an effective amount of a hydrophobic or amphiphilic compound to modify the diffusion of water into the matrix and the release of the therapeutic or prophylactic agent from the matrix, to a patient.

Please add the following new claims.

21. The method of claim 20 wherein the matrix is in the form of microparticles.

22. The method of claim 20 wherein the hydrophobic or amphiphilic compound is incorporated into the matrix at a ratio of between 0.01 and 60 by weight of hydrophobic compound to weight of polymer.

23. The method of claim 22 wherein the hydrophobic or amphiphilic compound is a lipid incorporated into the matrix at a ratio of between 0.01 and 30 (weight lipid/weight matrix material).

24. The method of claim 23 wherein the lipid is selected from the group consisting of fatty acids and derivatives, mono-, di and triglycerides, phospholipids, sphingolipids, cholesterol and steroid derivatives, oils, vitamins and terpenes.

25. The method of claim 24 wherein the lipid is a phospholipid selected from the group consisting of phosphatidic acids, phosphatidyl cholines with both saturated and unsaturated lipids, phosphatidyl ethanolamines, phosphatidylglycerols, phosphatidylserines, phosphatidylinositols, lysophosphatidyl derivatives, cardiolipin, and β-acyl-y-alkyl phospholipids.

26. The method of claim 25 wherein the phospholipid is selected from the group consisting of dioleoylphosphatidylcholine, dimyristoylphosphatidylcholine, dipentadecanoylphosphatidylcholine dilauroylphosphatidylcholine, dipalmitoylphosphatidylcholine, distearoylphosphatidylcholine,

diarachidoylphosphatidylcholine, dibehenoylphosphatidylcholine, ditricosanoylphosphatidylcholine, dilignoceroylphatidylcholine; and phosphatidylethanolamines.

27. The method of claim 20 wherein the agent is a therapeutic agent.

28. The method of claim 20 wherein the matrix is formed of a bioadhesive polymer.

29. The method of claim 20 wherein the matrix is formed of a polymer selected from the group consisting of poly(hydroxy acids), polyanhydrides, polyorthoesters, polyamides, polycarbonates, polyalkylenes, polyalkylene glycols, polyalkylene oxides, polyalkylene terepthalates, polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, polysiloxanes, poly(vinyl alcohols), poly(vinyl acetate), polystyrene, polyurethanes and co-polymers thereof, synthetic celluloses, polyacrylic acids, poly(butyric acid), poly(valeric acid), and poly(lactide-co-caprolactone), ethylene vinyl acetate, copolymers and blends thereof.

30. The method of claim 20 wherein the matrix is formed of a protein or polysaccharide.

31. The method of claim 20 wherein the matrix is in a pharmaceutically acceptable carrier for topical application or application to a mucosal surface.

32. The method of claim 20 wherein the matrix is in a pharmaceutically acceptable carrier for injection.

33. The method of claim 20 wherein the matrix is formulated for administration rectally or vaginally.

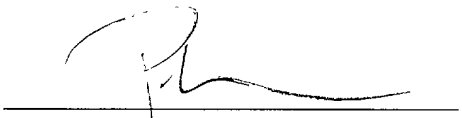
34. The method of claim 21 wherein the microparticles are formulated for pulmonary administration.

Please cancel claims 1-19.

Remarks

Claim 20 has been amended. Claims 1-19 have been canceled. New claims 21-34 have been added. Claims 20 was amended to incorporate the limitations of claim1 as originally filed. Support for new claims 21-34 can be found in claims 2-15 and 20 as originally filed.

Respectfully submitted,



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